K063117

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4. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Address of Manufacturer:	TEI Biosciences Inc. 7 Elkins Street Boston, MA 02127 (617) 268-1616 (617) 268-3282 (fax) ERN 3004170064
Contact Person:	Jeffrey Henderson Vice President, Quality and Regulatory Affairs Medtronic Neurosurgery 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1773 Fax: (805) 968-9336 ERN 2021898
Date:	October 12, 2006
Trade or Proprietary Name:	Durepair® Dura Regeneration Matrix
Common Usual or Classification Name:	Dura Substitute (882.5910)
Predicate Device Identification:	Durepair® Dura Regeneration Matrix (K041000 and K052211)

Description: The Durepair Dura Regeneration Matrix is a collagen implant for the repair of defects in the dura mater. Durepair is supplied sterile in sheet form in a variety of sizes to be trimmed and sutured by the surgeon to meet the individual patient's needs.

Intended Use: Durepair is a dura substitute for the repair of the dura mater.

Intended Use of Predicate Device(s): The predicate device, Durepair, is a dura substitute for the repair of the dura mater.

Technological Comparison: Medtronic Neurosurgery submits that the collagen material, fundamental scientific technological attributes, device labeling, and the intended use of the device are the same as the previously reviewed and cleared Durepair. Based upon the summary above, Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the Durepair product compared to the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2006

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
VP, Quality & Regulatory Affairs
125 Cremona Drive
Goleta, California 93117-5500

Re: K063117
Trade/Device Name: Durepair® Dura Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura substitute
Regulatory Class: II
Product Code: GXQ
Dated: October 12, 2006
Received: October 12, 2006

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson for
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Statement of Indications for Use

Indications for Use

510(k) Number (if known): K063117

Device Name: Durepair® Dura Regeneration Matrix

Indications for Use:

Durepair® is indicated as a dura substitute for the repair of the dura mater.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K063117